Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Applicant would like to thank Examiners Swope and Prouty for the courtesy extended to the undersigned representative during the telephone interview conducted on June 3, 2004. The substance of that interview is addressed below.

Initially, applicant would like to point out that the previously submitted amendment (dated March 11, 2004) was indicated in the advisory action as not having been entered. Therefore, substantially all amendments identified therein are re-presented by this amendment, with additional amendments to claim 1 having been made, as discussed during the above-noted telephone interview.

The amendment to the specification is made to correct three typographical errors appearing in the amended paragraph. The amendments to SEQ ID NO: 8 and SEQ ID NO: 12 find descriptive support in SEQ ID NO: 1 as filed. The remaining amendment harmonizes the span of the residues appearing in SEQ ID NO: 17 to the corresponding sequence within SEQ ID NO: 1. Therefore, no new matter has been entered. Please enter the corrected Sequence Listing that was submitted, along with a diskette containing the computer readable form and a Statement Under 37 CFR § 1.821, to the Patent and Trademark Office on March 11, 2004.

The rejection of claims 1, 2, and 8-12 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed in view of the above amendments and the following remarks.

Applicant submits that the addition of hybridization and wash conditions, and nucleotide sequence in claim 1 overcome the basis of the rejection by defining the scope of the term "biliverdin reductase."

Applicant also submits that the results achieved with the human BVR of SEQ ID NO: 2 are sufficiently predictive of results that would be expected when practicing the invention with other mammalian BVR. In support of this position, the previously submitted Declaration of Mahin D. Maines under 37 C.F.R. § 1.132 ("Maines Decl.") demonstrates that the structure and function of BVR proteins are highly conserved among mammalian BVR and, therefore, results achieved with human BVR are predictive of results that can be achieved with other mammalian BVR (Maines Decl. ¶¶ 4–11 and exhibits cited therein).

Thus, based upon the high degree of structural similarity of the three BVR proteins identified in the present application (confirmed by their high degree of structural similarity with mouse and pig BVR sequences and the functional similarity of many mammalian BVR proteins), persons of skill in the art would have expected results achieved with any one BVR protein as presently recited to be achievable, without undue experimentation, using other BVR proteins falling within the scope of the above-noted hybridization and wash conditions (*see* Maines Decl. ¶ 12).

In view of all of the foregoing, applicant submits that the rejection of claims 1, 2, and 8-12 under 35 U.S.C. § 112 as lacking enablement is improper and should be withdrawn.

The rejection of claims 1, 2, and 8-12 under 35 U.S.C. § 112 (first paragraph) as lacking written descriptive support is respectfully traversed.

Applicant submits that, with the amendment of claim 1 to recite hybridization and wash conditions, and the nucleotide sequence of SEQ ID NO: 2, the genus of a protein having the enzymatic activity of BVR is sufficiently defined to demonstrate that applicant was in possession of the claimed invention.

As noted previously, the present application sets forth not just one but three species within the scope of the presently recited genus. That the present application supports the language of claim 1 is entirely consistent with the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement, 66 Fed. Reg. 1099 (January 5, 2001) ("Written Description Guidelines"), because the present application describes "a representative number of species."

In addition to the foregoing and as further support for the fact that the three species are representative of the recited genus of BVR proteins, the Maines Declaration supports the conclusion that the structure and function of BVR proteins is highly conserved among mammalian BVR and, therefore, results achieved with human BVR are predictive of results that can be achieved with other BVR proteins within the scope of claim 1. In comparing the human BVR sequence (SEQ ID NO: 1) with the rat BVR sequence (SEQ ID NO: 4), and then comparing this alignment with the mouse and pig BVR sequences (*see* Maines Decl. ¶ 8), one of ordinary skill in the art would find that the high structural conservation indicates that the proteins are functionally quite similar (*see* Maines Decl. ¶¶ 7-10 and exhibits cited therein). The evidence is overwhelming that the three disclosed species appear to share identical hydrophobic domains, identical nucleotide binding domains, identical oxidoreductase domains, conserved leucine zipper domains, conserved kinase

motifs, identical nuclear localization signals, identical myristylation sits, conserved zinc finger domains, conserved PKC enhancing domains, and conserved PKC inhibiting domains. Biochemical pathways are also shared by the mammalian BVR proteins (Maines Decl. ¶ 11).

For these reasons, the genus of biliverdin reductase proteins or nucleic acid molecules encoding the same is sufficiently well described so as to reasonably convey to one skilled in the art that the applicant was in possession of the claimed invention.

Therefore, the rejection of claims 1, 2, and 8-12 under 35 U.S.C. § 112 as lacking written descriptive support is improper and should be withdrawn.

In view of all of the foregoing, applicant earnestly submits that this case is in condition for allowance.

Respectfully submitted,

Dated: June 15, 2004

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Ruth R. Smth
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